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10/552,287	01/04/2007	Anthony Futerman	30227	6293

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
04/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,287	FUTERMAN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2008 and 26 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *123,124,129 and 133-156* is/are pending in the application.

4a) Of the above claim(s) *139-156* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *123,124,129 and 133-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/1/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 123-124, 129, and 133-156 are pending in the application.

[2] Applicant's amendment to the claims, filed on 12/17/08, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicant's amendment to the specification, filed on 12/17/08, is acknowledged.

[4] Receipt of an information disclosure statement, filed on 2/1/09, is acknowledged.

[5] Receipt of a substitute Declaration under 37 CFR 1.63, filed on 1/26/09, is acknowledged.

[6] Applicant's remarks filed on 12/17/08 in response to the Office action mailed on 9/17/08 have been fully considered and are deemed to be persuasive to overcome at least one of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Rejections and/or objections to claims 125-128 and 130-132 are withdrawn in view of the instant claim amendment to cancel these claims.

[7] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Election/Restriction

[8] Claims 139-156 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 6/2/08.

Claim to Priority

[9] The instant application is a national stage filing under 35 U.S.C. 371 of PCT/IL04/00335, filed on 4/18/04, which claims domestic priority under 35 U.S.C. 119(e) to US provisional application 60/463,049, filed on 4/16/03.

[10] As noted in a prior Office action, regarding the domestic priority claim to provisional application 60/463,049, it is noted that 4/16/04 fell on a Friday, which does not appear to have been a Federal holiday, and thus this application was not filed within twelve months from the filing date of the provisional application, and there is no indication of an intermediate nonprovisional application that is directly claiming the benefit of the provisional application and filed within 12 months of the filing date of the provisional application.

Applicant is required to delete the reference to the prior-filed provisional application from the first sentence(s) of the specification or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish that this application, or an intermediate nonprovisional application, was filed within 12 months of the filing date of the provisional application.

[11] Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Israel application 156273, filed on 6/2/03. The certified copy has been filed in the instant application on 10/4/05.

While the foreign priority document appears to provide descriptive support for the limitations of claims 123-124 and 129, the examiner can find no support for the limitations of claims 133-138 in the foreign priority document.

[12] Accordingly, claims 123-124 and 129 are accorded a priority date of 6/2/03, while claims 133-138 are accorded a priority date of 4/18/04.

RESPONSE TO ARGUMENT: Beginning at p. 12 of the instant remarks, applicant argues the IL 156273 application provides adequate descriptive support for the limitations of pending claims 129 and 133-138.

Applicant's argument is not found persuasive. The examiner acknowledges that the IL 156273 application provides adequate descriptive support for the limitations of claim 129, however maintains that the IL 156273 application fails to provide adequate descriptive support for the limitations of claims 133-138.

Regarding claim 133, applicant relies on the IL 156273 application disclosure "...glucocerebrosidase molecule having normal enzymatic activity..." (IL 156273 application at p. 15) as supporting the limitations of claim 133. However, this disclosure fails to support the recited range of "*about* the same capacity" (emphasis added) in claim 133.

Regarding claim 134, applicant relies on the IL 156273 application disclosure "...oligosaccharide chains of glycosylated N-linked glycosylation sites modified to terminate in mannose sugars..." (IL 156273 application at p. 55) as supporting the

limitations of claim 134. However, this disclosure fails to support the recited range of "*at least one* exposed mannose residue" (emphasis added) in claim 134.

Regarding claim 135, there appears to be no descriptive support for glucocerebrosidase molecules being capable of being internalized by a phagocyte and applicant fails to show support for such limitation in the IL 156273 application.

Regarding claims 136-138, applicant relies on the IL 156273 application disclosure "The compound…can be formulated as the active ingredient of a pharmaceutical composition comprising suitable carriers and/or diluents…suitable for therapeutically correcting the impaired enzymatic activity of the mutant glucocerebrosidase molecule…" (IL 156273 application at p. 26) as supporting the limitations of claim 136-138. However, this disclosure fails to support the recited "*disease associated with* glucocerebrosidase deficiency" (emphasis added) in claims 136 and 138. This disclosure also fails to support the recited routes of administration in claim 137 and further fails to support an "...article of manufacture comprising packaging material..." in claim 138.

Information Disclosure Statement

[13] All references cited in the IDS filed on 2/1/09 have been lined through as all of the cited references are duplicates of those already cited in Form PTO-892 mailed on 9/17/08. A copy of Form PTO/SB/08 is attached to the instant Office action.

Oath/Declaration

[14] The objection to the oath or declaration filed is withdrawn in view of the substitute Declaration under 37 CFR 1.63, listing the citizenship of each inventor.

Specification/Informalities

[15] The objection to the title of the invention as not being descriptive is withdrawn in view of the instant specification amendment to amend the title.

[16] The objection to the disclosure as containing embedded hyperlinks and/or other form of browser-executable code is withdrawn in view of the instant specification amendment to delete hyperlinks.

[17] The objection under 37 CFR 1.52(e)(4) because the transmittal letter does not contain a statement that the two submitted compact discs are identical is withdrawn in view of applicant's statement at p. 16, middle of the instant remarks.

[18] The objection to the specification as not containing an incorporation by reference statement for compact discs is withdrawn in view of the instant specification amendment at p. 5, bottom.

[19] As noted in the prior Office action, in order to perfect compliance with the rules for a sequence listing, applicant is required to submit a formal amendment to the specification in accordance with 37 CFR 1.121, directing entry of the substitute sequence listing paper copy filed on 1/4/07 into the application. Applicant's request in the remarks section at p. 16, middle, is acknowledged, however, this request is not an amendment to the specification.

Claim Objections

[20] The objection to claim 123 in the recitation of "glycoylated" is withdrawn in view of the instant claim amendment.

[21] Claim 134 is objected to in the recitation of "glycosylation moiety" and in order to improve claim form it is suggested that the noted phrase be replaced with, *e.g.*, "glycosylation residue".

Claim Rejections - 35 USC § 112, Second Paragraph

[22] The rejection of claim 124 as being indefinite in the recitation of "resolution of 2.9 angstroms or higher" is withdrawn in view of the instant claim amendment to recite "resolution of 2.9 angstroms or greater resolution".

[23] The rejection of claims 129 and 133-138 as being confusing in the recitation of "glycosylation residues 2, 3, and 4 of said amino acid sequence" is withdrawn in view of the instant claim amendment to claim 129.

Claim Rejections - 35 USC § 112, First Paragraph

[24] The written description rejection of claim(s) 123-124, 129, and 133-138138 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See paragraph 23 beginning at p. 9 of the Office action mailed on 9/17/08.

RESPONSE TO ARGUMENT: Beginning at p. 17 of the instant remarks, applicant essentially argues the rejection is obviated by amendment to the claims to limit the structural coordinates, the sequence of the polypeptide, the space group, and the unit cell dimensions.

Applicant's argument is not found persuasive. Regarding claims 129 and 133-138, as noted in the prior Office action at p. 10, bottom, and undisputed by applicant, the claims encompass both a crystalline and a non-crystalline "preparation". While it is acknowledged that claim 129 recites the limitation, "...said glucocerebrosidase is able to form pure glucocerebrosidase crystals...", it is well-known in the prior art that crystals can be used as "seeds" for producing additional crystals. See, *e.g.*, US Patent 7,442,537 at column 6, lines 19-24.

Regarding claims 123-124, 129, and 133-138, it is noted that the recited glucocerebrosidase molecule is recited as "having the amino acid sequence...SEQ ID NO:1", where the transitional phrase "having" has been interpreted as being equivalent to "comprising". Thus, the "glucocerebrosidase molecule" is a genus, encompassing those that are limited to SEQ ID NO:1 as well as those that have any additional amino acid sequence(s) at the N- and/or C-terminal ends of SEQ ID NO:1. However, as noted by McPherson et al. (cited in Form PTO-892 mailed on 9/17/08) in the previous Office action at p. 19, bottom, "Every protein is different in its properties and, surprisingly perhaps, this applies even to proteins that differ by no more than one or just a few amino acids", which is undisputed by applicant. See also the references of Tonetti et al. (*Acta Crystallogr D Biol Crystallogr* 54:684-687, July 1998) and Somers et al. (US

Patent Application Publication 20070038380 A1), each reference teaching a crystal of an *E. coli* GFS whose sequence is only different by only two amino acids at the C-terminal end, yet each crystal has a different space group and/or unit cell dimensions.

Also, it is noted that the "glucocerebrosidase molecule" is recited as being "...unglycosylated at one or more glycosylation residues...corresponding to Asn59, Asn146 and Asn 270..." Thus, glycosylation of the "glucocerebrosidase molecule" of as many as two of residues Asn59, Asn146 and Asn270 is optional. However, it is well-known in the prior art that glycosylation of even a single residue in a protein can be *critical* to crystal formation. See, *e.g.,* Hogg et al., Acta Cryst. (2002). D58, 1734-1739, 2002 at p. 1737, column 2. Also, it is well-known in the prior art that deglycosylation can be an important prerequisite for achieving protein crystallization. See, *e.g.,* Kalisz et al., *J. Mol. Biol.* 213:207-209, 1990.

In this case, the specification discloses only a single representative species of a non-crystalline glucocerebrosidase polypeptides as encompassed by claims 129 and 133-138, *i.e.,* non-crystalline, deglycosylated SEQ ID NO:1, prepared according to the method as disclosed at p. 80, lines 5-16. Also, the specification discloses only a single representative species of crystals of glucocerebrosidase as encompassed by claims 123-124, 129, and 133-138, *i.e.,* a crystal of deglycosylated SEQ ID NO:1 as prepared according to the method as disclosed at p. 80, lines 5-16, having the space group $C222_1$ and the unit cell dimensions a=107.7 Å b=285.2 Å, c=91.8 Å that diffracts x-rays to a resolution of 2.0 Å. Other than these single disclosed species of the respective genus of non-crystalline or crystalline glucocerebrosidase polypeptides, the

specification fails to disclose any other species of non-crystalline or crystalline glucocerebrosidase polypeptides as encompassed by the claims.

In this case, the specification discloses only a single representative species of a non-crystalline glucocerebrosidase polypeptides as encompassed by claims 129 and 133-138, *i.e.,* non-crystalline, deglycosylated SEQ ID NO:1, prepared according to the method as disclosed at p. 80, lines 5-16. Also, the specification discloses only a single representative species of crystals of glucocerebrosidase as encompassed by claims 123-124, 129, and 133-138, *i.e.,* a crystal of deglycosylated SEQ ID NO:1 as prepared according to the method as disclosed at p. 80, lines 5-16, having the space group $C222_1$ and the unit cell dimensions a=107.7 Å b=285.2 Å, c=91.8 Å that diffracts x-rays to a resolution of 2.0 Å. Other than these single disclosed species of the respective genus of non-crystalline or crystalline glucocerebrosidase polypeptides, the specification fails to disclose any other species of non-crystalline or crystalline glucocerebrosidase polypeptides as encompassed by the claims.

One of skill in the art would not accept the single representative species of the genus of recited non-crystalline or crystalline polypeptides as being representative of all non-crystalline and crystalline polypeptides as encompassed by the claims. As such, the specification, taken with the pre-existing knowledge in the art of protein crystallography, fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.

[25] The scope of enablement rejection of claims 123-124, 129, and 133-138 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See paragraph 24 beginning at p. 13 of the Office action mailed on 9/17/08.

RESPONSE TO ARGUMENT: Beginning at p. 19 of the instant remarks, applicant argues: 1) the claims have been amended to limit the structure coordinates, the sequence of the polypeptide, the space group, and the unit cell dimensions; 2) the experimentation required to make the claimed crystalline polypeptides is "definitely of a routine...nature, easily carried out by unskilled technicians or robots"; and 3) crystallization success rate can be "significantly improved using the information provided by their analysis".

Applicant's argument is not found persuasive. Regarding argument 1), the examiner acknowledges the claim amendment, however, maintains the position that the specification fails to enable the full scope of the claimed invention. As noted above, regarding claims 129 and 133-138, as noted in the prior Office action at p. 10, bottom, and undisputed by applicant, the claims encompass both a crystalline and a non-crystalline "preparation". While it is acknowledged that claim 129 recites the limitation, "...said glucocerebrosidase is able to form pure glucocerebrosidase crystals...", it is well-known in the prior art that crystals can be used as "seeds" for producing additional crystals. See, *e.g.*, US Patent 7,442,537 at column 6, lines 19-24.

Regarding claims 123-124, 129, and 133-138, it is noted that the recited glucocerebrosidase molecule is recited as "having the amino acid sequence...SEQ ID

NO:1", where the transitional phrase "having" has been interpreted as being equivalent to "comprising". Thus, the "glucocerebrosidase molecule" is a genus, encompassing those that are limited to SEQ ID NO:1 as well as those that have any additional amino acid sequence(s) at the N- and/or C-terminal ends of SEQ ID NO:1.

Regarding arguments 2) and 3), while applicant takes the position that crystallizing a polypeptide requires no more than routine experimentation, the prior art of record as cited in the prior Office action at pp. 16-20 clearly suggests otherwise. Even applicant acknowledges that prior attempts to crystallize CEREZYME "have essentially failed" (specification at p. 5, lines 7-12). Moreover, while applicant attempts to rely on a teachings of the use of robots for conducting crystallization trials, applicant's reliance on such teachings is misplaced, particularly as these teachings speak only to the use of robots in crystallization trials and fail to teach or suggest that crystallization is easy and routine as asserted by applicant. The teachings of Drenth (prior Office action at p. 17, top) in addition to the other prior art of record cited in the previous Office action clearly support a position of unpredictability in protein crystallization, noting that such experimentation is "mainly a trial-and-error procedure", dependent upon each protein, the conditions of which cannot be predicted *a priori*. Regarding the use of advancing technology, *e.g.,* robots, in determining crystallization conditions, as noted by Kundrot in the prior Office action at p. 19 and undisputed by applicant, crystallization strategies continue to be rooted in unpredictable trial-and-error approaches (p. 525, column 1, bottom). Here, the specification discloses only a single working example of a non-crystalline glucocerebrosidase polypeptide as encompassed by claims 129 and 133-

138, *i.e.,* non-crystalline, deglycosylated SEQ ID NO:1, prepared according to the method as disclosed at p. 80, lines 5-16. Also, the specification discloses only a single working example of a crystal of glucocerebrosidase as encompassed by claims 123-124, 129, and 133-138, *i.e.,* a crystal of deglycosylated SEQ ID NO:1 as prepared according to the method as disclosed at p. 80, lines 5-16, having the space group $C222_1$ and the unit cell dimensions a=107.7 Å b=285.2 Å, c=91.8 Å that diffracts x-rays to a resolution of 2.0 Å. Other than these single working examples, the specification fails to provide any guidance for achieving diffraction-quality crystallization of other glucocerebrosidase polypeptides as encompassed by the claims.

As noted above, McPherson et al. (cited in Form PTO-892 mailed on 9/17/08) teaches "Every protein is different in its properties and, surprisingly perhaps, this applies even to proteins that differ by no more than one or just a few amino acids", which is undisputed by applicant. See also the references of Tonetti et al. (*Acta Crystallogr D Biol Crystallogr* 54:684-687, July 1998) and Somers et al. (US Patent Application Publication 20070038380 A1), each reference teaching a crystal of an *E. coli* GFS whose sequence is only different by two amino acids at the C-terminal end, yet each crystal has a different space group and/or unit cell dimensions.

Also, it is noted that the "glucocerebrosidase molecule" is recited as being "...unglycosylated at one or more glycosylation residues...corresponding to Asn59, Asn146 and Asn 270..." Thus, glycosylation of the "glucocerebrosidase molecule" of as many as two of residues Asn59, Asn146 and Asn270 is optional. However, it is well-known in the prior art that glycosylation of even a single residue in a protein can be

critical to crystal formation. See, *e.g.,* Hogg et al., Acta Cryst. (2002). D58, 1734-1739, 2002 at p. 1737, column 2. Also, it is well-known in the prior art that deglycosylation can be an important prerequisite for achieving protein crystallization. See, *e.g.,* Kalisz et al., *J. Mol. Biol.* 213:207-209, 1990.

Taken together, the prior art clearly acknowledges a high level of unpredictability in the art of protein crystallization and the specification fails to provide sufficient guidance to enable a skilled artisan to make all non-crystalline and crystalline polypeptides as encompassed by the claims.

Claim Rejections - 35 USC § 102/103

[26] The rejection of claim 129 under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dvir (cited as reference U in the Form PTO-892 mailed on 9/17/08) is withdrawn in view of applicant's amendment to claim 129. The limitations of claim 129 are adequately supported by the prior-filed foreign priority document, Israel application 156273, filed on 6/2/03. As such, the reference of Dvir, having an earliest public availability date of 6/3/03, is no longer available as prior art under 35 U.S.C. 102.

[27] The rejection of claim(s) 133-137 under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dvir (cited as reference U in the Form PTO-892 mailed on 9/17/08) is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See

paragraph 25 beginning at p. 23 of the Office action mailed on 9/17/08. As noted above, claims 133-137 are accorded a priority date of 4/18/04.

RESPONSE TO ARGUMENT: Beginning at p. 20 of the instant remarks, applicant argues the rejection is obviated by an attached Declaration under 37 CFR 1.132.

Applicant's argument is not found persuasive. The examiner has reviewed each of the papers filed in the application file following the Office action mailed on 9/17/08 and has made an earnest attempt to locate a Declaration under 37 CFR 1.132 attached to applicant's response filed on 12/17/08. However, such a Declaration cannot be located in the application file. As such, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

[28] The rejection of Claim 138 under 35 U.S.C. 103(a) as being unpatentable over Dvir is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See paragraph 26 beginning at p. 24 of the Office action mailed on 9/17/08. As noted above, claim 138 is accorded a priority date of 4/18/04.

RESPONSE TO ARGUMENT: Beginning at p. 20 of the instant remarks, applicant argues the rejection is obviated by an attached Declaration under 37 CFR 1.132.

Applicant's argument is not found persuasive. The examiner has reviewed each of the papers filed in the application file following the Office action mailed on 9/17/08 and has made an earnest attempt to locate a Declaration under 37 CFR 1.132 attached to applicant's response filed on 12/17/08. However, such a Declaration cannot be located in the application file. As such, the rejection is maintained for the reasons of record.

Conclusion

[29] Status of the claims:

- Claims 123-124, 129, and 133-156 are pending the application.
- Claims 139-156 are withdrawn from consideration.
- Claims 123-124, 129, and 133-138 are rejected.
- No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/
Primary Examiner, Art Unit 1656